FDA Patient Safety News: Show #1, February 2002

FDA Clears External Defibrillator For Use on Young Children

FDA recently cleared for marketing an external defibrillator system with a special pad that's designed to be used on infants and young children who experience cardiac arrest. The system is made by the Heartstream Division of Philips Medical Systems. Like other defibrillators, this system delivers an electric shock through the chest wall to the heart.

The difference is that other defibrillating devices on the market are restricted to adults or children over the age of eight. The pads on this device deliver about a third of the electrical energy of an ordinary pad, so they can be used on infants and children up to 55 pounds.

These pads aren't used in quite the same way as adult pads. When defibrillators are used on adults, both pads are positioned on the chest. But with these pediatric pads, one is on the chest, and the other on the back. To be sure the user selects the right pads in an emergency, the pediatric pads are imprinted with a picture of a child, and they show how the pads are to be positioned, one up and one down. Likewise, the connector is pink and shaped like a teddy bear.

Additional Information:

New Device Clearances:Heartstream FR2 AED with Attenuated Defibrillation Pads K003819. May 2, 2001.
httphttp://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm088983.htm

---

FDA Approves New Glucose Test for Adult Diabetics

FDA recently approved a new product designed to periodically monitor glucose levels in diabetic patients. And the good news is that it does it without a needle stick. It looks something like a wristwatch. In fact, it's called the "Glucowatch Biographer," and it's made by a California company named Cygnus.

The way it works is that a small electrical current from the device extracts a tiny amount of fluid through the skin. Then a sensor on the back of the watch measures the glucose level in this fluid every 20 minutes for 12 hours. These glucose measurements are stored in the device and can be read by the patient. If the patient's glucose level reaches dangerously high or low levels, an alarm sounds.

A couple of important things to remember. First, this device isn't intended to replace the regular blood glucose meter. It's supposed to be used with it to help detect trends and patterns in glucose levels. Finger-stick tests will still be needed to calibrate the device, and at other times to cross-check a patient's glucose levels.

And for now, the device should only be used by patients over 18, since it's only approved for adults.

Additional Information:

New Device Approvals: Glucowatch® Automatic Glucose Biographer - P990026. March 22, 2001.
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm089158.htm

---

New Device for Procedures on Diseased Bypass Grafts

A new device recently cleared for marketing by FDA is designed to help prevent complications when angioplasty or stenting is done in coronary saphenous vein bypass grafts. The new device prevents debris such as thrombi and cholesterol crystals from being swept down the vein graft into the heart, where it could block downstream vessels. During the angioplasty and stenting procedures, the device occludes the vessel, and then blood and debris are aspirated into a syringe. The device is made by Percu Surge, Incorporated, a division of Medtronic Ave.

Restenosed vein grafts are not an insignificant problem. About half a million people have coronary bypass vein grafts every year and it's estimated that at least half of them will form blockages in those vein grafts over a ten year period, leading to more treatment, such as angioplasty or stenting. And that's when this device comes into play.

Additional Information:

New Product Clearances: Percusurge Guardwire Temporary Occlusion and Aspiration System. June 1, 2001.
http://www.accessdata.fda.gov/cdrh_docs/pdf/k013913.pdf

New Device for Procedures on Diseased Bypass Grafts

A new device recently cleared for marketing by FDA is designed to help prevent complications when angioplasty or stenting is done in coronary saphenous vein bypass grafts. The new device prevents debris such as thrombi and cholesterol crystals from being swept down the vein graft into the heart, where it could block downstream vessels. During the angioplasty and stenting procedures, the device occludes the vessel, and then blood and debris are aspirated into a syringe. The device is made by Percu Surge, Incorporated, a division of Medtronic Ave.

Restenosed vein grafts are not an insignificant problem. About half a million people have coronary bypass vein grafts every year and it's estimated that at least half of them will form blockages in those vein grafts over a ten year period, leading to more treatment, such as angioplasty or stenting. And that's when this device comes into play.

Additional Information:

JAMA article: New Device for Procedures on Diseased Bypass Grafts. August 1, 2001.
http://jama.ama-assn.org/cgi/content/extract/286/5/527-a?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=New+Device+for+Procedures+on+Diseased+Bypas

---

Preventing Deaths and Serious Injuries From Medical Gas Mix-Ups

The FDA recently issued a warning about the possibility of patient injuries and deaths from mix-ups with medical gases, particularly oxygen, that come in cryogenic containers.

We issued the warning because we've received a number of reports of deaths and injuries that occurred when patients were accidentally given the wrong gas. That is, another gas, like nitrogen or carbon dioxide, was connected to the oxygen supply system. That occurred despite the fact that the gas supply systems that deliver gas to patients have special connectors that only fit the appropriate gas containers. That means an oxygen container will only fit onto the oxygen connector on the gas supply system. So there's supposed to be a built-in safeguard. But in these cases, this safeguard was bypassed and a gas other than oxygen was mistakenly hooked up to the oxygen connector on the supply system and delivered to the patient.

Considering this safeguard, what went wrong?

In the cases we looked at, two errors were usually made in sequence. First, in most of the cases, a container of gas other than oxygen was mistakenly delivered to the facility, and sometimes it was misidentified as containing oxygen. Then someone tried to connect this gas container - the one they thought contained oxygen - to the oxygen supply system. Of course this didn't work, because of the safeguard we talked about. And so they then over-rode the safeguard by changing the connector on the gas container so it would fit the oxygen connector on the gas delivery system.

There are things you can do to prevent such things from happening.

* - First, never use adapters or change the connectors or the fittings on gas containers. If a connector on a container won't attach readily to the connector on your gas supply system, it's probably the wrong gas - don't try to connect it.
* - Second, when connecting a medical gas container, check the label carefully to ensure that it contains the right gas.
* - Third, be sure that all personnel who handle medical gases are properly trained to examine and recognize medical gas labels.
* - Finally, if your facility receives both medical and industrial grade gases, store them separately.

Additional Information:

FDA Public Health Advisory: Potential for Injury from Medical Gas Misconnections of Cryogenic Vessels. July 20, 2001.
hhttp://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/UCM062189

Patient Death Illustrates Importance of MRI Room Precautions

FDA Patient Safety News: Show #1, February 2002

We'd like to review a widely publicized incident, first because it serves as a stark reminder of what can happen when our medical systems fail, and second, because talking about tragic events such as this one may help prevent the same kind of thing from happening again.

In this case, an oxygen tank the size of a fire extinguisher became magnetized in an MRI room, flew across the room, and killed a six year old boy who was in the MRI machine.

This isn't the first time this kind of thing has happened. An article in a recent issue of the American Journal of Roentgenology describes five accidents in the past 15 years, including four in the past three years, where oxygen tanks were brought into MRI rooms and killed patients.

And oxygen tanks aren't the only problem. Any object made of metal that can be magnetized can become a deadly projectile if it's near an MRI machine, and that includes scissors, traction weights and even hairpins. Also, if the MRI patient has a metal implant, it can twist and cause damage.

People sometimes don't think about it, but tattoos and tattooed eyeliner sometimes contain iron compounds, and they can become magnetized and burn the patient. And so can EKG leads and other cables that might be lying near the patient.

There are lots of things you can do to avoid these kinds of accidents. Some of the most obvious are to screen everyone entering the MRI room and check on what they're bringing with them. Of course you have to understand which items might contain even small amounts of metals that can be magnetized. You can also hang posters in the MRI suite reminding patients and personnel about the hazards.

Safer Use of Central Venous Catheters

We want to alert you to the possibility of two potentially serious safety problems when using central venous catheters, or CVC's. In fact they're sometimes called "the deadly duo" of central venous catheterization.

We're talking here about cardiac perforation and tamponade. According to a recent FDA article in the International Journal of Trauma Nursing, those two events account for almost half of the reported deaths associated with CVC's.

What causes the problem? One of the experts quoted in the article points out that the tip of a CVC can potentially perforate any surface it lies against, and so it's important to keep the tip away from certain areas such as the right atrium, where it can damage the endocardium. This expert also notes that CVC's placed in the antecubital veins are more likely to produce cardiac perforation because the catheter can move into the right atrium. And that movement occurs when the patient moves.

In fact, patient movement is a key element in explaining this problem. Another expert quoted in the article estimates that the CVC tip can move as much as eight centimeters when the patient raises the catheterized arm.

Still another expert in the article says that cutting off the tip of the CVC, which is sometimes done in an effort to make cannulation easier, can increase the risk of perforation.

The article also points out how difficult it can be to recognize cardiac perforation and tamponade in a patient with a CVC. Symptoms can occur suddenly, or they can take days to show up. And they can be confused with other illnesses and traumas.

There are a wide variety of clinical symptoms associated with tamponade. They include neck vein distention, sudden onset of cyanosis, bradycardia, tachycardia, rising central venous pressures, right heart failure, hypotension, decreasing pulse pressures, distant heart sounds, restlessness, confusion, nausea, and epigastric discomfort. That's a lot of signs and symptoms, some of them contradictory, and they're not specific to tamponade.

And to make matters even more difficult, there may not be any symptoms at all. In fact, sudden death can occur in the absence of any clinical warning signs. And so one of the experts in the article advocates considering a diagnosis of tamponade in any patient with a CVC who develops sudden deterioration in cardio-respiratory status.

That's important, because although these incidents are often fatal if left untreated, early diagnosis and prompt intervention can often save the patient's life.

And that treatment has three key elements, according to one of the experts. First, stop all fluid infusions through the existing CVC if you suspect perforation or tamponade. Second, try to drain fluid out through the CVC. And third, remove the CVC slowly.

But the best solution to this problem is avoiding it in the first place. And so the question is how do you prevent perforation and tamponade in patients who have CVC's. And here there are two key elements: first, locating the catheter properly, and second, keeping it from migrating.

When it comes to location, the article says to keep the tip of the catheter out of the right atrium, preferably locating it in the distal superior vena cava. One of the experts suggests that the tip of the CVC should be no lower than two centimeters below an imaginary line between the lower surfaces of the ends of the clavicles.

And to keep the catheter from migrating, the article cautions to keep the patient's movements to a minimum. Every time the cannulated arm, head and neck bends and flexes, the catheter tip can advance a little more towards the right atrium.

Additional Information:

See Related Article Below.

Article: "Ethical Issues in Whistleblowing"

In our Journal Scan feature, we report on articles that are particularly relevant to patient safety.

This time we want to call your attention to an editorial in the september 5th 2000 issue of JAMA, entitled "Ethical Issues in Whistleblowing," by Dr. Norman Fost.

The author discusses the reasons people sometimes give for not reporting medical errors when they happen, and he counters those with ethical reasons for reporting. The editorial focuses largely on incidents involving human error, but the underlying ethical issues would also apply to adverse events caused by problems with equipment.

Additional Information:

Additional information: Journal of the American Medical Association (JAMA) article. September 2001.
http://jama.ama-assn.org/cgi/content/extract/286/9/1079?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=Ethical+Issues+in+Whistleblowing&searchid=1&

FDA Looking for Experts to Advise Agency

We want to ask you to help us, by sharing with us your knowledge and expertise.

For many years, FDA has relied on the recommendations of outside advisory committees to help us make sound decisions on medical devices. Advisory committee members are experts in a given specialty who take time out from their own professional lives to provide us with independent scientific and medical advice on the safety, effectiveness, and appropriate use of medical devices - sometimes under controversial circumstances.

Our medical device panels need expertise in a wide variety of clinical specialty areas, including cardiology, orthopedics, radiology, and immunology. If you, or someone you know, would be interested in serving on an FDA advisory panel, please go to our website for more information.

Additional Information:

FDA Advisory Committees in the Center for Devices and Radiological Health
http://www.fda.gov/AboutFDA/CentersOffices/CDRH/default.htm